

**Notice of Allowability**

Application No.

10/743,402

Applicant(s)

PORUBCAN, RANDOLPH  
STANLEY

Examiner

Lakia J. Tongue

Art Unit

1645

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 8/16/05.
2.  The allowed claim(s) is/are 1-6, 8-13, 28 and 29 (renumbered claims 1-14, respectively).
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some\*    c)  None    of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets" ) must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948 ) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>8/25/05; 9/6&amp;13/05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                                       |
|   | 9. <input type="checkbox"/> Other _____.   |

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Eric Mirabel on September 13, 2005.

2. This Office Action is responsive to Applicant's response filed August 16, 2005. All rejections of record are withdrawn in view of Applicant's response. Claims 1-6, 8-13 and 28-29 (1-14, respectively) are allowed.

3. The application has been amended as follows:

*In the Specification:* RELATED APPLICATIONS

This application claims priority to U.S. Provisional Application Serial No. 60/439,887, filed January 14, [2002] 2003.

*In the Claims:*

Claim 5 (currently amended) The formulation of claim 1 wherein the probiotic bacteria is from the *Lactobacillus* or *Bifidobacterium* genera.[.]

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Claim 8 (currently amended) The formulation of claim 1 which is encapsulated and wherein the [capsule materials are] encapsulated formulation is made of gelatin[,] or cellulose [or the capsules include Hydroxypropyl Methylcellulose are Vcaps<sup>TM</sup>.

4. The following is an examiner's statement of reasons for allowance. The prior art cited neither teaches nor suggest a formulation comprising probiotic bacteria with monovalent alginate salts, wherein the formulation has a water activity of between 0.01-0.07, and wherein, upon exposure to an acid environment, an alginic acid gel is formed which shields the probiotic bacteria from antibiotic effects if the acidic environment.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lokia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LJT

September 12, 2005



**LYNETTE R. F. SMITH**  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

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**Clean Copy of Specification**

**RELATED APPLICATIONS**

This application claims priority to U.S. Provisional Application Serial No. 60/439,887, filed January 14, 2003.

**Clean Copy of Claims**

1. A formulation comprising probiotic bacteria with monovalent alginate salts, wherein the formulation has a water activity of between 0.01-0.07, and wherein, upon exposure to an acidic environment, an alginic acid gel is formed which shields the probiotic bacteria from the antibiotic effects of the acidic environment.
2. The formulation of claim 1 which does not include alginate salts of divalent metals, in quantities such that the shielding alginic acid gel does not form.
3. The formulation of claim 1 wherein the water activity is 0.028 or less.
4. The formulation of claim 1 wherein the monovalent alginate salts are sodium alginate or potassium alginate.
5. The formulation of claim 1 wherein the probiotic bacteria is from the *Lactobacillus* or *Bifidobacterium* genera.
6. The formulation of claim 1 wherein the formulation reacts with acidic environment to generate alginic acid.

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8. The formulation of claim 1 which is encapsulated and wherein the encapsulated material is made of gelatin or cellulose.
9. The formulation of claim 8 wherein the capsule materials do not include any alginates salts in them.
10. The formulation of claim 1 wherein the alginate salt is dried to a moisture content below 5% prior to mixing with probiotic bacteria.
11. The formulation of claim 8 wherein the probiotic bacteria are present at a concentration of  $10^7$  to  $10^{11}$  cfu per capsule.
12. The formulation of claim 3 wherein the weight ratio of sodium alginate in the formulation is 10-99%.
13. The formulation of claim 11 wherein the weight ratio of sodium alginate in the formulation is 20% to 60%.
28. The formulation of claim 1 including grapeskin extract.
29. The formulation of claim 2 wherein the alginate salts of divalent metals are magnesium alginate or calcium alginate.